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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,337	06/13/2000	TORLEIF OVE BJORNSEN		1608

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Ms. Virginia Griffith
1288 Pear Avenue
Mountain View, CA 94043

21
EXAMINER

LUDLOW, JAN M

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 08/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/509,337

Applicant(s)

BJORNSON ET AL

Examiner

Jan M. Ludlow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 57-68 is/are pending in the application.
- 4a) Of the above claim(s) 57-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 64-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 October 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 19-20. 6) ☐ Other:

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1. Restriction is required under 35 U.S.C. 121 and 372.
2. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.
3. Group I, claim(s) 57-63, drawn to a method of electrophoresis assay.
4. Group II, claim(s) 64-68, drawn to an apparatus.
5. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The apparatus used in the method requires a detection region, but does not require the sample supply reservoir, sample drain reservoir, elution buffer reservoir, analyte waste reservoir or separation channel of the apparatus. Further, the common features of the apparatus of the apparatus claims and the apparatus used in the method do not constitute a "special technical feature" in that such features are known in the prior art. See the rejection under 35 USC 103 below.
6. Newly submitted claims 57-63 are directed to an invention that is independent or distinct from the invention originally claimed for the above reasons.
7. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 57-63 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

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8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

11. Determining the scope and contents of the prior art.
12. Ascertaining the differences between the prior art and the claims at issue.
13. Resolving the level of ordinary skill in the pertinent art.
14. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 64-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parce '470.

17. Parce '470 teaches a microfluidic electroosmotic device having two or more parts. A first planar element has channels molded or embossed therein (col. 5, line 21) and a second planar element is bonded to the first element to cover the channels (col. 6, lines 1-21). Plural devices may be made simultaneously by embossing/molding substrate sheets (col. 5, lines 24-26). The elements are polymeric and may be non-rigid (col. 6, line 23), constituting the instant films. The device is elongate and has a network of channels as shown in Figure 2. Buffer reservoirs 210, 21 are coupled to waste reservoir 208 via channel 204 (col. 12, lines 13-44). Sample reservoirs 220, 226 are provided, as is analyte waste reservoir 228 (col. 14, lines 1-7). Electrophoretic separation is taught (col. 13, line 23). Ports, e.g., holes in a layer of the device, are provided for access to the reservoirs (col. 10, lines 1-10). Electrodes may be provided as a coating (layer or lamina) on the elements (col. 10, lines 30-35) and coatings may be provided to change the electrical characteristics of the elements (col. 8, lines 22-29).

18. Parce '470 fails to explicitly teach an elongate flexible laminate having plural devices.

19. It would have been obvious to make the device of Parce from non-rigid (flexible) polymers, constituting the instant films, in order to make a non-rigid element for suitable uses as taught by Parce '470. It would have been obvious to make plural devices on

sheets as taught by Parce for mass manufacture and to make the sheets rectangular (elongate) in order to fit more devices than on a square sheet in accordance with general principles of geometry. With respect to plastics, it would have been obvious to use known polymers for their known properties. With respect to the number of devices in an array, it would have been obvious to place any suitable number of devices on a sheet in order to ease manufacturing and/or use, e.g., in order to use a standard size embossing machine, or standard size sheet of plastic stock, or standard size sample applicator or reader. It would have been obvious to locate an electrode on either film element in order to contact the fluid contained therein as taught by Parce '470. With respect to the separation channel, it is the examiner's position that the channel of Parce '470 is capable of separation. Alternatively, it would have been obvious to provide a separation channel in order to perform electrophoresis as taught by Parce '470.

20. Applicant's arguments filed June 24, 2003 have been fully considered but they are not persuasive.

21. Applicant argues that the examiner "merely states that it would be obvious to make the device of Parce from non-rigid (flexible) materials." This is not the case. The examiner has carefully pointed out in Parce ('470) where it is suggested to make the devices of non-rigid materials (see, e.g., page 3, paragraph 7 of the last Office Action, and col. 6, line 23 of Parce). It would have been obvious to make the devices non-rigid because Parce teaches to do so, also noted by the examiner on lines 6-7 of page 4 of the previous Office Action. Since "rigid" means "inflexible", "non-rigid" means "flexible". Applicant argues that there is no teaching of arrays of microchannel structures, but

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again, the examiner has carefully pointed out the exact portion of Parce that teaches this aspect of the invention (see, e.g., page 3, paragraph 7 of the last Office Action, and col. 5, lines 24-26 of Parce). Applicant argues that Parce ('470) does not teach substrates that can be rolled or folded prior to use, but Parce ('071) has been relied upon for such teaching and the instant claims do not recite this limitation. Applicant argues that the emphasis by Parce ('470) on a single device teaches away from the instant plurality of devices, but this argument is not persuasive in that teaching how one device is used teaches how each of the plural devices stamped onto a single sheet as taught by Parce ('470) would function.

22. Applicant argues that Parce ('071) teaches storage of samples for loading into a single device, whereas the instant invention requires addition of separate samples to separate devices. This argument is not persuasive because Parce ('470) is relied upon for the plural devices, and Parce ('071) was merely relied upon for the teaching of arranging plural devices in an elongate flexible strip that can be rolled for storage. Note that the claims are no longer directed to folded or rolled devices.

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (703) 308-4039. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



Jan M. Ludlow

Primary Examiner

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August 27, 2003